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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/435,247 11/05/99 SORNASSE

T PA-0020 US

HM12/0709

Incyte Pharmaceuticals Inc  
3174 Porter Drive  
Palo Alto CA 94304

EXAMINER

WOODWARD, M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED:

07/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/435,247	SORNASSE ET AL.
	Examiner Mary K Zeman	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 25 May 2001.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims 1-20 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) Notice of References Cited (PTO-892)      18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)      19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      20) Other: \_\_\_\_\_

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 6-7 and 18-20, drawn to a set of polynucleotides (1-516) and their use in a hybridization assay for detection of those polynucleotides, classified in class 435, subclass DIG 37.
- II. Claims 2-5 and 11-13, drawn to isolated polynucleotides (1-243), vectors, host cells, and methods of producing a recombinant protein, classified in class 536, subclass 23.1.
- III. Claims 8 and 9, drawn to methods of screening a library of compounds with a set of polynucleotides, classified in class 435, DIG 17.
- IV. Claim 10, drawn to methods of purifying ligands which bind to an isolated polynucleotide, classified in class 435, subclass 6.
- V. Claim 14, drawn to an isolated polypeptide or fragment thereof, classified in class 530, subclass 350.
- VI. Claims 15-16, drawn to methods of screening a library with a polypeptide, classified in class 435, subclass DIG: 15.
- VII. Claim 17, drawn to methods of purifying a ligand which binds an isolated polypeptide, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct in that they are differing compositions of matter. Invention I calls for a composition of more than 500 polynucleotides, while Invention II is drawn to a single isolated polynucleotide. While some of the sequences may overlap between the two inventions, the differing compositions would require different types of searches which are not necessarily coextensive in scope. As such, it would pose an undue burden upon the examiner if not restricted.

Inventions I/II and III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the polynucleotides can be used in subtractive hybridization for forming a new library of polynucleotides.

Inventions I/II and V are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group V, the critical feature is a polypeptide whereas for Group I/II the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group V to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I/II and V supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I/II and VI/VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions cannot be used together. The polynucleotides of Inventions I or II are not useable in the methods of Inventions VI or VII.

Inventions III and IV and VI and VII are each separate and distinct from one another as they are drawn to differing methods, having differing steps, components and differing ultimate goals. As such, the searches for the two inventions would not be co-extensive in scope, placing an undue burden upon the examiner if not restricted.

Inventions III/IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions cannot be used together. The polypeptides of Inventions V are not useable in the methods of Inventions III or IV.

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Inventions V and VI/ VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Invention V can be used to induce an immunological response for the production of antibodies..

*Sequence Election Requirement Applicable to All Groups*

**In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single polynucleotide sequence.**

**In regards to Invention I, the set of polynucleotides, a single sequence must be elected from the recited 1-516. If that sequence is novel, then the combination of sequences is also novel. Similarly, a single sequence must be elected for the Inventions using the set of polynucleotides in other methods.**

**In regards to Inventions II and V, a single sequence must be elected from 1-243 for nucleic acids, and from a polypeptide encoded by 1-243 for Invention V. Similarly, a single sequence must be elected for any of the other methods using an isolated polypeptide or isolated polynucleotide.**

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

In view of the present state of Office Resources, the search and examination of more than one sequence is deemed to impose an undue burden upon the office and strained office resources, therefore, Applicant must elect a single sequence to be searched. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences

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will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A fully responsive reply will comprise both an election of an Invention, and a specific sequence to be searched.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Woodward whose telephone number is (703) 308-4028. The examiner can generally be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

The official fax number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524.

mkz  
7/2/01

  
MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
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